EXHIBIT 3a

IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NORTHEASTERN DIVISION

WILMA S. CARTER and LAWRENCE CARTER, Plaintiffs, v. AMERIDOSE, LLC, MEDICAL SALES MANAGEMENT, INC., MEDICAL SALES MANAGEMENT SW, INC., GDC PROPERTIES MANAGEMENT, LLC, ARL BIO PHARMA, INC. D/B/A ANALYTICAL RESEARCH LABORATORIES, BARRY J. CADDEN, GREGORY CONIGLIARO, LISA CONIGLIARO CADDEN, DOUGLAS CONIGLIARO, CARLA CONIGLIARO, GLENN A. CHIN, SPECIALTY SURGERY CENTER, PLLC and KENNETH R. LISTER, M.D., Defendants.	)	Case No. JURY DEMAND

COMPLAINT AND JURY DEMAND

NOW COME Plaintiffs, Wilma S. Carter and Lawrence Carter, by and through undersigned counsel, and for their causes of action file this complaint for damages against the above-named Defendants alleging the following:

INTRODUCTION

1. In 2012, a widespread outbreak of fungal meningitis injured people in more than 20 states and caused at least 64 deaths at the time of the filing of this Complaint. Over 750 people have been diagnosed with meningitis, abscesses or other related illnesses.

2. The United States Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC") identified fungus present in several separate lots of

preservative-free injectable steroids, specifically, methylprednisolone acetate (sometimes referred to as "MPA") and other drugs, that were compounded and distributed by New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") as the cause of the fungal meningitis outbreak and the resulting injuries and deaths.

3. Multiple vials of MPA, along with other medications developed at NECC have been recalled, but the recall was too late for Plaintiff Wilma S. Carter, and for many others who have suffered serious and catastrophic injuries or death.

PARTIES

4. Plaintiff, Wilma S. Carter (hereinafter "Mrs. Carter" or "Plaintiff"), is a citizen and resident of Cumberland County, Tennessee and lives at 1591 Sawmill Road, Crossville, Tennessee 38555.

5. Plaintiff, Lawrence Carter (herein after "Mr. Carter"), is a citizen and resident of Cumberland County, Tennessee and lives at 1591 Sawmill Road, Crossville, Tennessee 38555.

6. Plaintiffs, Lawrence Carter and Wilma S. Carter, are and, at all times relevant, were husband and wife.

7. Defendant, Ameridose LLC ("Ameridose") is a Massachusetts limited liability company with a principal place of business at 203 Flanders Road, Westborough, Massachusetts 01581. The managers of Ameridose are Gregory Conigliaro and Barry Cadden. Ameridose's registered agent is Gregory Conigliaro.

8. Defendant Medical Sales Management, Inc. ("MSM") is a Massachusetts corporation with its principal place of business at 697 Waverly Street, Framingham, MA 01702. Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director

and Gregory Conigliaro is the Secretary and Director. MSM's registered agent is Gregory Conigliaro.

9. Defendant Medical Sales Management SW, Inc. ("MSMSW") is a Massachusetts corporation with its principal place of business at 697 Waverly Street, Framingham, MA 01702. Douglas Conigliaro is the President and Director, Barry Cadden, is the Treasurer and Director, Gregory Conigliaro is the Secretary and Director and Lisa Conigliaro Cadden is Director. MSMSW's registered agent is Gregory Conigliaro.

10. Defendant GDC Properties Management, LLC ("GDC") is a Massachusetts limited liability company with a principal place of business at 701 Waverly Street, Framingham, Massachusetts 01702. GDC's manager and registered agent is Gregory Conigliaro.

11. Defendant ARL BioPharma, Inc. d/b/a Analytical Research Laboratories ("ARL") is an Oklahoma corporation with a principal place of business at 840 Research Parkway, Suite 546, Oklahoma City, Oklahoma 73104. The Chief Executive Officer and registered agent of ARL is Thomas Kupiec.

12. Defendant Gregory Conigliaro ("Gregory Conigliaro") is an individual person residing at 1 Mountain View Drive, Framingham, Massachusetts 01701. Gregory Conigliaro is a principal owner and the general manager of NECC, as well as NECC's Treasurer, Secretary, Vice President, registered agent, and one of its Directors. Gregory Conigliaro provided financial advice, oversaw operations, and regularly appeared in the NECC facility. Gregory Conigliaro is also the founder and a Manager of Ameridose and involved in Ameridose's day-to-day operations. Gregory Conigliaro is also Secretary and Director of MSM and MSMSW.

13. Defendant Douglas Conigliaro ("Douglas Conigliaro") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Douglas Conigliaro is Director and

President of MSM and MSMSW. Douglas Conigliaro provided advice, oversaw day-to-day operations and regularly appeared in the MSM/MSMSW facility.

14. Defendant Carla Conigliaro ("Carla Conigliaro") is an individual person residing at 15 Hale Drive, Dedham, Massachusetts 02026. Carla Conigliaro is one of the Directors of NECC and the wife of Douglas Conigliaro.

15. Defendant Barry Cadden ("Barry Cadden") is an individual person residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Barry Cadden was at all relevant times, the President and Director of New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"), which is a Massachusetts corporation. At least until October 2012, Barry Cadden was NECC's licensed Pharmacist Manager of Record, as that term is defined by 247 CMR 2.00, and upon information and belief, compounded MPA at NECC. Barry Cadden was also a founder and Manager of Ameridose and was involved in Ameridose's day-to-day operations. Barry Cadden was also the Treasurer and Director of MSM and MSMSW.

16. Defendant Lisa Conigliaro Cadden ("Lisa Cadden") is an individual person residing at 13 Manchester Drive, Wrentham, Massachusetts 02093. Lisa Cadden is a board member, Director and, at least until October 2012, a pharmacist at NECC. Lisa Cadden, upon information and belief, compounded drugs and was involved in the day-to-day operations of NECC.

17. Defendant Glenn A. Chin ("Glenn Chin") is an individual person residing at 173 Mechanic Street, Canton, Massachusetts 02021. At least until October 2012, Glenn Chin was a pharmacist at NECC. Glenn Chin, upon information and belief, compounded drugs, including MPA, at NECC.

18. Defendant Specialty Surgery Center, PLLC ("Specialty Surgery") is a Tennessee

company organized and domesticated under the laws of the State of Tennessee with its principal place of business in Crossville, Tennessee. Specialty Surgery's registered agent for service of process is Donathan M. Ivey, 116 Brown Avenue, Crossville, Tennessee 38555-7703.

19. Defendant Kenneth R. Lister, M.D. ("Dr. Lister") is an individual residing at 8317 Neubert Springs Road, Knoxville, TN 37920-9410 and a citizen and resident of the State of Tennessee. During all relevant times, Dr. Lister was an employee of the Defendant Specialty Surgery. Dr. Lister is a medical doctor and practices in the specialty of pain management. Dr. Lister was involved in the day to day operations at Specialty Surgery.

20. At all times while providing treatment to Wilma S. Carter at Specialty Surgery, the physicians, nurses, staff, and other personnel were agents, apparent agents, employees or representatives of Specialty Surgery and were acting within the course and scope of their employment, agency, or apparent agency with Specialty Surgery.

21. Pursuant to the doctrine of *respondeat superior*, Specialty Surgery is vicariously liable for any negligent acts and omissions of its employees, agents, or representatives committed in the course and scope of their employment or agency while treating Wilma S. Carter.

22. The individuals and entities described in paragraphs 7–17 are sometimes collectively referred to as the "NECC Related Defendants."

23. The individuals and entities described in paragraphs 18–21 are sometimes collectively referred to as the "Tennessee Defendants."

JURISDICTION AND VENUE

24. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. § 1334(b) because as described herein each claim asserted herein is related to a case under Title

11.

25. This case is related to the NECC Bankruptcy because the outcome of the proceeding certainly could have some effect on the bankruptcy estate.

26. On December 21, 2012, NECC filed a petition for Bankruptcy protection under Chapter 11 of the Bankruptcy Code: In re: New England Compounding Pharmacy, Inc., Debtor, United States Bankruptcy Court for the District of Massachusetts Case no. 12-19882 HJB. A United States Trustee was subsequently appointed to administer the Bankruptcy Estate.

27. NECC has express contractual indemnification obligations to among others, Barry Cadden, Gregory Conigliaro, Lisa Cadden, Carla Conigliaro, Glenn Chin, GDC, and MSM. Some if not all of the aforementioned individuals are insureds under NECC's insurance policies.

28. Adversarial cases seeking recovery of damages for the benefit of the bankruptcy estate and its unsecured creditors have been filed in NECC's bankruptcy against each of the NECC Related Defendants.

29. Lawsuits alleging death or injury based on contaminated MPA have been filed around the country. On February 12, 2013, the Judicial Panel on Multidistrict Litigation (MDL No. 2419) issued an order under 28 U.S.C. § 1407 transferring various federal-court proceedings to the United States District Court for the District of Massachusetts for coordinated or consolidated pretrial proceedings. The transferred actions are pending in the United States District Court for the District of Massachusetts in the Multidistrict Litigation action styled: In re: New England Compounding Pharmacy, Inc. Products Liability Litigation, United States District Court, District of Massachusetts, MDL No. 1:13-md-2419-FDS. The transferred cases have been assigned to the Honorable F. Dennis Saylor, United States District Judge, for pre-trial proceedings and coordination.

30. The Bankruptcy Court for the District of Massachusetts has established a deadline of January 2014 for the filing of claims against NECC's bankruptcy estate in In re: New England Compounding Pharmacy, Inc.

31. Upon information and belief, all of the Tennessee Defendants presently intend to seek, and will seek, relief from the stay in order to pursue contribution or indemnity claims against NECC for all or some portion of the damages sought by this Complaint. In addition or in the alternative, all of the Tennessee Defendants presently intend to file, and will file, claims in NECC's bankruptcy proceeding seeking indemnification or contribution for all or some portion of the damages sought by this Complaint.

32. The Plaintiffs will file a claim against NECC in its bankruptcy proceeding for the injuries at issue in this Complaint.

33. By Order dated May 31, 2013, Judge Saylor, ruled that the New England Compounding Pharmacy, Inc., Multi District Litigation Court has subject-matter jurisdiction over any cases pending in federal court or state court against entities or individuals "affiliated" with NECC whether or not NECC is named as a defendant. Those NECC affiliated entities and individuals referred to by Judge Saylor in his May 31, 2013 Order include the defendants described in paragraphs 7-17.

34. In addition or in the alternative to the bases for jurisdiction already asserted, this Court has subject-matter jurisdiction over all claims against the Tennessee Defendants pursuant to 28 U.S.C. § 1367 in that all such claims are so related to claims in this action within the original jurisdiction of this Court that they form part of the same case or controversy under Article III of the United States Constitution.

35. Venue is proper and appropriate in the United States District Court for the Middle

District of Tennessee pursuant to 28 U.S.C. § 1391(b)(2) in that all or a substantial part of the events and actions giving rise to the matters asserted in the Complaint occurred in Cumberland County, Tennessee.

36. At all times relevant the Defendants were engaged in the business of developing, compounding, marketing, distributing, promoting, selecting, purchasing, and/or selling or administering, either directly or indirectly, steroids in the State of Tennessee from which they derived significant and regular income.

37. Defendants are subject to the jurisdiction of this Court in that they are generally present in Tennessee, have transacted business within the State of Tennessee, and acting individually and/or through their agents and employees have committed tortious actions and omissions in Cumberland County, Tennessee, that have proximately caused the injuries that are the subject of this lawsuit.

38. The NECC Related Defendants described in paragraphs 7-17 are further subject to the jurisdiction of this Court as a result of contracting to supply goods and things in Tennessee, by conducting or soliciting business in Tennessee, by engaging in a persistent course of conduct in Tennessee, and by deriving substantial revenue from goods used or consumed or services rendered in Tennessee.

STATEMENT OF THE FACTS

A. RELEVANT BACKGROUND

39. NECC was a compounding pharmacy that compounded, distributed and/or sold drugs to pharmacies in many states throughout the United States, including Tennessee.

40. Upon information and belief, NECC was a privately-held company that was owned and controlled by Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro, Barry

Cadden, and Lisa Cadden.

41. At least until October 2012, Barry Cadden was a licensed pharmacist. In addition to being NECC's President, Barry Cadden also was NECC's licensed Pharmacist Manager of Record. Upon information and belief, Barry Cadden compounded medications, including MPA, at NECC.

42. "Manager of Record or Pharmacist Manager of Record," as defined by 247 CMR 2.00, "means a pharmacist, currently registered by the [Massachusetts] Board [of Registration in Pharmacy] pursuant to 247 CMR 6.07, who is responsible for the operation of a pharmacy or pharmacy department in conformance with all laws and regulations pertinent to the practice of pharmacy and the distribution of drugs."

43. One of the Massachusetts regulations promulgated by the Massachusetts Board of Registration in Pharmacy pertinent to NECC's operation as a compounding pharmacy mandated that "[t]he premises of the pharmacy or pharmacy department shall at all times be kept in a clean and sanitary manner." 247 CMR 6.02(1).

44. At least until October 2012, Gregory Conigliaro was involved in co-managing the day-to-day operations of NECC, MSM, MSMSW, Ameridose, and GDC.

45. At least until October 2012, Lisa Cadden was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC.

46. At least until October 2012, Glenn Chin was a licensed pharmacist who, upon information and belief, compounded medications, including MPA, at NECC.

47. According to an application signed by Gregory Conigliaro and filed with the Massachusetts Board of Registration in Pharmacy on May 14, 2012, Ameridose is a "distribution

center to entities of common ownership – currently Ameridose and NECC, as well as other Properly Licensed Facilities in the future."

48. Since it was formed as a limited liability company in 2006, Ameridose has been controlled by NECC. In 2005, NECC hired and paid Sophia Pasedis, a member of the Massachusetts Board of Registration in Pharmacy, to consult with NECC on the formation and establishment of Ameridose.

49. On April 11, 2011, Ameridose employee, Michelle Rivers, upon information and belief at the direction of the NECC principals, requested certification for pharmacy technicians employed by NECC for use in an inspection of NECC's facilities by the Massachusetts Board of Registration in Pharmacy.

50. On or about August 24, 2012, Ameridose posted an employment opportunity for Registered Pharmacists to work for NECC in Framingham, Massachusetts. In the posting, potential applicants were told to contact mlord@medicalsalesmgmt.com. Upon information and belief, there were many other occasions where employees of Ameridose, MSM and/or MSMSW would perform services for NECC at the direction of NECC's principals.

51. Between 2006 and the present, Ameridose and NECC would often share a booth at conferences and conventions with a single banner listing both company names. During that same time, Ameridose and NECC would hold an annual Christmas party for employees of both companies.

52. Both Ameridose and NECC were controlled by Conigliaro and Cadden family members. MSM and/or MSMSW printed materials for and marketed both NECC's and Ameridose's products, including MPA. One former employee of MSM and/or MSMSW stated: "I didn't think there was any difference [between Ameridose and NECC]."

53. Through September 2012, both NECC and Ameridose used MSM and/or MSMSW for sales and marketing functions. NECC's privacy policy on its website referred to the "Ameridose Privacy Policy." In 2012, NECC salespersons recommended NECC's "sister company," Ameridose, for drug compounds that NECC did not have available.

54. MSM and/or MSMSW shared office space owned by GDC Properties with NECC in Framingham, Massachusetts.

55. According to its Internet website, "ARL is a dynamic contract research organization providing high quality analytical work and problem solving to the pharmaceutical industry."

56. According to its Internet website, ARL offers "a full range of laboratory services, both analytical and microbiological" and "strives to collaborate with the compounding pharmacists, by helping them improve the quality of the compounds they prepare through meticulous analysis, data interpretation and troubleshooting."

57. ARL also states on its Internet website that it follows "USP monographs/general chapters[,]" and that it has a formal Quality Assurance Program in compliance with "USP monographs/general chapters[.]"

58. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states: "Your customers have high expectations of you and your compounding pharmacy. You offer exceptional service and quality preparations that are compounded to exacting specifications. ***You should expect nothing less from the testing laboratory you entrust.***" (emphasis is original).

59. In marketing its laboratory testing services to compounding pharmacies such as NECC, ARL states that ARL's "**[t]esting methods and technologies [are] unparalleled in the**

market today[.]" (emphasis in original).

60. Upon information and belief, ARL provided sterility testing services and information to NECC for its compounded medications, including MPA.

61. With respect to its sterility tests, ARL, on its Internet website, states: "We examine each sterility test for growth at days 2, 3, 7 and 14 and log the results. If a test shows no evidence of microbial growth in either media over the 14 day incubation period, then it complies with the test for sterility. A preliminary sterility report is available after 72 hours of incubation."

62. GDC, which is an acronym for "Gregory D. Conigliaro," owns the real property and is responsible for maintenance and structural improvements at 685-705 Waverly Street, Framingham, Massachusetts.

63. From 1998 until at least October 2012, GDC leased a portion of the premises at Waverly Street to NECC, MSM and MSMSW.

64. In an on-line posting for a property management position at GDC, which appeared on or before October 25, 2012, GDC stated that it "owns an 88,000 square foot facility on seven acres in downtown Framingham. GDC currently has eight major tenants." GDC describes one of the duties and responsibilities of the GDC property manager as follows: "Insure all tenants operate their businesses in accordance with facility, local [and] state …rules and regulations."

65. GDC maintained a high degree of control over the premises leased by NECC.

66. Until October 2012, NECC, Ameridose, ARL, Barry Cadden, Lisa Cadden and Glenn Chin compounded, tested, marketed and/or distributed MPA. MPA is a steroid that is used, *inter alia*, to treat neck and back pain. MPA is administered via spinal-area injection to patients with neck and back pain.

67. GDC and Gregory Conigliaro knew that NECC was compounding MPA at 697 Waverly Street, and further knew that this medication was injected into humans and was required to be sterile.

68. Until October 2012, NECC compounded MPA at its facility in Framingham, Massachusetts, and NECC sold MPA to healthcare providers in more than 20 states across the country.

69. On September 21, 2012, the CDC was notified by the Tennessee Department of Health of a patient with the onset of meningitis following an epidural steroid injection. It was later determined that the patient had fungal meningitis.

70. According to the CDC, fungal meningitis occurs when the protective membranes covering the brain and spinal cord are infected with a fungus. Fungal meningitis is rare and usually caused by the spread of a fungus through blood to the spinal cord. Fungal meningitis is not transmitted from person to person.

71. According to the CDC, symptoms for meningitis include the following: new or worsening headache, fever, sensitivity to light, stiff neck, new weakness or numbness in any part of the body, slurred speech, and increased pain, redness or swelling at the injection site. Death may result from meningitis.

72. According to the CDC, symptoms of fungal meningitis are similar to symptoms of other forms of meningitis; however, they often appear more gradually and can be very mild at first. In addition to typical meningitis symptoms, like headache, fever, nausea, and stiffness of the neck, people with fungal meningitis may also experience confusion, dizziness, and discomfort from bright lights. Patients might just have one or two of these symptoms.

73. In late September 2012, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml that it had compounded and sold: Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #05212012@68, BUD 11/17/2012; Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #06292012@26, BUD 12/26/2012; and Methylprednisolone Acetate (PF) 80 mg/ml Injection, Lot #08102012@51, BUD 2/6/2013.

74. The FDA identified Specialty Surgery Center in Crossville, Tennessee as one of the healthcare facilities that received vials of MPA that were part of the September 2012 recall. Specialty Surgery Center is also the location where Plaintiff Wilma S. Carter was injected with NECC's MPA.

75. On October 6, 2012, NECC announced that it was recalling "all products currently in circulation that were compounded at and distributed from its facility in Framingham, Massachusetts."

76. In NECC's October 6, 2012, press release, NECC advised that it was "notifying its customers of this recall by fax[,]" and that "[c]linics, hospitals and healthcare providers that have product which is being recalled should stop using the product immediately, retain and secure the product, and follow instructions contained in the fax notice."

77. In NECC's October 6, 2012, press release, NECC explained that "[p]roducts from NECC can be identified by markings that indicate New England Compounding Center by name or by its acronym (NECC), and/or the company logo.

78. On or about October 3, 2012, the Massachusetts Department of Public Health ("DPH") secured the surrender of NECC's license to operate as a compounding pharmacy.

79. On or about October 8, 2012, at the request of DPH, Barry Cadden and Glenn Chin voluntarily ceased their practice as pharmacists until at least December 31, 2012. Lisa

Cadden also has voluntarily ceased her practice as a pharmacist until at least December 31, 2012. Upon information and belief, none of them have practiced as a pharmacists since voluntarily ceasing their practice.

80. On or about October 22, 2012, the Massachusetts Board of Registration in Pharmacy authorized DPH to request the voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, Lisa Cadden and NECC. According to DPH, "[i]f the three pharmacists and NECC do not comply, the Board authorized staff to proceed with permanent revocation."

81. Over the last ten years, ARL has conducted sterility testing on samples of methylprednisolone acetate compounded by NECC, including samples from Lot #05212012@68, BUD 11/17/2012; Lot #06292012@26, BUD 12/26/2012; and Lot #08102012@51, BUD 2/6/2013.

82. From May through August 2012, NECC sent several samples of its methylprednisolone acetate to ARL for sterility testing. As one example, on or about May 21, 2012, NECC sent to ARL two 5ml vials of methylprednisolone acetate from a batch of 6,528 vials that came from Lot 05212012@68, which had been compounded by NECC on May 21, 2012.

83. On May 22, 2012, ARL received and tested the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012. ARL sent to NECC a Microbiology Report dated May 25, 2012, which stated that the two vials had been tested on May 22, 2012.

84. ARL's May 25, 2012 Microbiology Report to NECC stated that the "preliminary" results from the sterility test using test method USP 71 showed that the two 5ml vials of methylprednisolone acetate that NECC sent to ARL on or about May 21, 2012, were "sterile."

ARL's report to NECC further noted that the preliminary results were observed "after approximately 72 hours of incubation."

85. Pursuant to the protocols of test method USP 71, sterility testing on a batch of more than 6,000 vials of methylprednisolone acetate should have been conducted on at least 20 vials from the batch.

86. On or about August 10, 2012, NECC caused one 5ml vial of methylprednisolone acetate to be sent to ARL for sterility testing from a batch of several thousand vials that are from Lot #08102012@51, BUD 2/6/2013.

87. The Microbiology Reports issued by ARL to NECC between May and September 2012 concerning the sterility testing of methylprednisolone acetate indicated that the sterility tests performed by ARL were to be conducted in compliance with USP 71.

88. During the summer of 2012, MSM and/or MSMSW sales representatives, on behalf of NECC and Ameridose, distributed copies of the May 25, 2012, ARL Microbiology Report concerning the testing of the vials of methylprednisolone acetate from Lot 05212012@68 to customers and/or potential customers in a packet of marketing materials intended to highlight the safety and sterility of the methylprednisolone acetate compounded by NECC.

89. ARL was well aware of the sterility risks posed by compounding pharmacies, specifically including the sterility risks posed by NECC's compounding practices.

90. In 2002, ARL found that four samples of a steroid compounded by NECC were contaminated with potentially deadly endotoxins.

91. In 2005, ARL's Chief Executive Officer, Thomas Kupiec, wrote in a published article that "there have been reports of tragedies resulting from a lack of quality control in the compounding pharmacy."

92. In 2007, Kupiec also recognized the dangers of not testing a sufficient number of samples when he wrote in a published article that "one of the recognized limitations of sterility testing is sample size."

93. In May 2007, the FDA issued a consumer update entitled, "The Special Risks of Pharmacy Compounding[,]" which stated that there had been "more than 200 adverse events involving 71 compounded products since 1990. Some of these instances had devastating repercussions."

94. In 2007, despite being aware of the risks to human health posed by compounding pharmacies, Kupiec advocated for relaxing the USP Quality Assurance Standards for compounding pharmacies. Noting USP 71's requirements of "a minimum number of articles to be tested in relation to the number of articles in the batch" and a "14-day quarantine of the drug to await final test results[,]" Kupiec wrote in a 2007 published article that there should be "separate standards for compounding pharmacies and manufacturers."

95. While the requirements of USP 71 were not relaxed for compounding pharmacies after Kupiec's 2007 published article, ARL allowed compounding pharmacies such as NECC to submit an inadequate number of samples for sterility testing, which practice did not comply with USP 71 requirements.

96. Other testing laboratories that perform sterility testing on drugs compounded by compounding pharmacies request double the number of samples required by USP 71.

97. Between January 2012 and August 2012, NECC's environmental monitoring program for its compounding facility yielded numerous microbiological isolates (bacteria and mold) within the Clean Room used for the production of MPA. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa

Cadden and Glenn Chin knew or should have known of these findings. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to investigate those isolates and made no effort to identify those isolates. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to perform any product assessments for the products made in the Clean Room where the isolates were found. NECC, Ameridose, GDC, MSM and/or MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin failed to take any corrective actions with regards to the isolates that were found. Despite these findings, NECC continued to compound MPA, and Ameridose, MSM and/or MSMSW continued to distribute marketing materials to customers and potential customers touting the cleanliness of the NECC laboratories.

B. NECC RELATED DEFENDANTS IGNORED SAFETY STANDARDS BY PRODUCING DRUGS IN A NON-COMPLIANT FACILITY

98. The Massachusetts Department of Public Health and FDA investigators identified serious deficiencies and significant violations at NECC that placed the public's health and safety at risk. Each Agency has released reports on Defendants' longstanding widespread disregard for safety. Some examples follow. The conditions were so bad, FDA issued a Form 483 identifying eight pages of observed conditions or practices that may indicate violations of the Federal Food, Drug and Cosmetic Act, or related regulations.[1] The findings reveal repulsive conditions where bacteria and mold fester throughout the NECC facility and equipment.

99. In early October 2012, FDA investigators located fungal contamination in a sealed vial of MPA at NECC's facilities on GDC's property. FDA's findings prompted NECC

[1] Plaintiffs are not asserting a private cause of action based on any FDA regulations.

to recall 17,676 single-dose vials of MPA.

100. Even though NECC recalled the MPA in early October, thousands of people at outpatient clinics and similar facilities in more than 20 states were injected with the steroid between July and September 2012.

101. The Massachusetts Department of Public Health (DPH) investigators, in collaboration with investigators from the U.S. Food and Drug Administration (FDA), investigated NECC and released preliminary findings on October 23, 2012.

102. As an initial matter, the DPH: "Upon beginning the joint on-site investigation of NECC early in this outbreak, DPH and FDA investigators identified serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk."

103. In its preliminary findings the DPH found: "During the facility inspections, investigators documented serious health and safety deficiencies related to the practice of pharmacy." The DPH noted:

1. NECC distributed two of the recalled lots of methylprednisolone acetate (PF) 80 MG/ML prior to receiving results of sterility testing:

    a. Lot *06292012@26* was prepared on June 29, 2012. Final sterility testing was completed on July 17, 2012. Two shipments of product were made prior to the final sterility tests results being received.

    b. Lot *08102012@51* was prepared on August 10, 2012. Final sterility testing was completed on August 28, 2012. Eleven shipments of product were made prior to the final sterility tests results being received.

2. Final sterilization of product did not follow proper standards for autoclaving (sterilization through high pressure steam) pursuant to United States Pharmacopeia Standard 797 (USP 797) and NECC's own Standard Operating Procedures: Examination of NECC records indicated a systemic failure to keep products in the autoclave for the required minimum 20-minute sterilization period necessary to ensure product sterility.

3. NECC did not conduct proper validation of autoclaves pursuant to USP 797: NECC failed to test their autoclaves to ensure proper function.

4. Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate from Lot *08102012@51*.

5. Powder hoods, intended to protect pharmacists from inhaling substances during medication preparation, within the sterile compounding area were not thoroughly cleaned pursuant to USP 979. Residual powder was visually observed within the hood during inspection. This contamination may subsequently lead to contamination of compounded medications.

6. Condition of "Tacky" mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry, violated the USP 797. Mats were visibly soiled with assorted debris.

7. A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth: "A pool of water was visually observed around the boiler and adjacent walls, creating an unsanitary condition; the culture results of this potential contaminant are still pending."

104. Surface samples from NECC's "clean" rooms revealed bacterial and mold, as did various equipment and parts of the facility. Air sampling showed "1 big mold" as far back as May 29, 2012. Air sampling throughout the facility revealed mold and bacteria. Dozens of results exceeded the "action level." "There was no investigation conducted by the firm when levels exceeded their action limits and there was no identification of the isolates. No documented corrective actions were taken to remove the microbial contamination (bacterial and mold) from the facility."

105. Environmental monitoring procedures require sampling. Records showed mold and bacterial. "These results were not investigated and there was no identification of the isolates. There were no product impact assessments performed for any sterile products that were made in the hoods or gloveboxes on the days the samples were taken. In addition, the firm has no evidence that any corrective actions were taken to prevent contamination of the sterile drug products."

106. FDA observed greenish yellow discoloration lining the interior surface of the viewing lens within the "Inside" autoclave used for steam sterilization of various components and equipment (e.g. vials of multiple sizes, stoppers, and spin bars) used in the formulation of sterile drug products. FDA further observed condensation along the interior surfaces of the "Outside" autoclave to collect in a pool at the base of the chamber.

107. The investigators also observed problems with NECC's ability to maintain its clean room, which is the enclosed space that is designed and maintained to have a controlled environment with law levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of microbial contamination.

108. A used mattress processing facility, also owned by the Conigliaro family, abuts and operates under the same roof as NECC's facility. As FDA noted in its inspection, "The firm is abutted to the rear and along the left parking area by a recycling facility that handles such materials as mattresses and plastics. On 10/02/2012, the area was observed to include large equipment (e.g. excavators and freight trucks) producing airborne particulates (e.g. dust). Rooftop units serving the firm's HVAC system were estimated to be located approximately 100 feet from the recycling facility."

109. FDA observed what appeared to be white filamentous substances covering the HVAC return located behind the autoclave located in the firm's Middle Room (ISO 7). This autoclave is used for the steam sterilization of formulated bulk drug suspensions. FDA further observed greenish residue covering the surface of the ceiling exposed to the filter above, within Weigh Station 3 Hood located in the firm's ISO 6 Clean Room. The firm uses Weigh Station

Hoods to weigh active ingredients and other raw materials utilized in the formulation of sterile drug preparations.

110. In sum, FDA observed bacteria and mold growing all over the firm's "sterile" facility, one it repeatedly represented to customers was "state-of-the-art" and used to produce "highest quality compounded medications."

111. MSM and/or MSMSW marketed and Ameridose and/or distributed the products compounded in such deplorable conditions.

C. NECC RELATED DEFENDANTS DISREGARDED PRIOR COMPLAINTS AND INSPECTIONS BY CONTINUING IMPERMISSIBLE CONDUCT AND IGNORING SAFETY RISKS

112. Defendants effectively ignored dozens of complaints from as early as April 1999. In 2002, two patients suffered an adverse effect after taking an NECC compounded steroid used to treat joint pain and arthritis. One victim subsequently died. FDA notified the state pharmacy board in October 2002 about an incident involving a drug the company had produced, methylprednisolone acetate, which is the same steroid that caused the current outbreak.

113. In 2004, an inspector report revealed that a toxin had been found in an NECC drug and that the company could not produce various records about the drug, including test results on its sterility. NECC and other Defendants failed to meet accepted standards that year for making the same steroid.

114. A 2006 letter to NECC from Pharmacy Support Inc., an outside evaluation firm, observed that the company continued to have significant gaps in its sterile compounding operation. That same year FDA issued warning letters to NECC. NECC and other Defendants received other warnings as well.

115. NECC and other Defendants solicited out-of-state prescriptions for office use and

used unapproved forms. NECC and other Defendants were aware of complaints regarding this practice and its improper promotional material and methods, but turned a blind eye to it all.

D. TENNESSEE DEFENDANTS DECISION TO PURCHASE MPA FROM NECC

116. The Tennessee Defendants, its agents and employees, knew or should have known of the dangers of using compounded drugs and specifically products compounded by NECC. These defendants failed to undertake any appropriate due diligence to ascertain the safety and quality of NECC's products.

117. Instead, the only motivation for the Tennessee Defendants to purchase steroids in bulk from NECC was price.

118. The Tennessee Defendants made the decision to purchase MPA in bulk from NECC was because it was the cheapest steroid.

119. The Tennessee Defendants did not conduct appropriate due diligence or investigation into NECC before deciding to purchase and administer NECC compounded steroids to their patients. The Tennessee Defendants placed their own profits over patient safety.

120. NECC was not authorized to compound and sell MPA in bulk to Specialty Surgery.

121. NECC was only allowed to fill individual prescriptions for individual patients written by appropriately licensed healthcare providers.

122. Upon information and belief, Specialty Surgery did not use patient-specific individual prescriptions when buying MPA from NECC in bulk.

123. Specialty Surgery could have purchased MPA for use in ESI's from a compounder other than NECC.

124. Specialty Surgery could have purchased MPA for use in ESI's from a

pharmaceutical manufacturer, e.g. Pfizer.

125. The Tennessee Defendants knew, or should have known, that NECC produced drugs they administered to Plaintiff without preservatives.

126. The Tennessee Defendants knew or should have known that purchasing and utilizing preservative free products, as was done here, increased the risk of contamination. Because the vials contained no antimicrobial preservative, there was nothing to inhibit the growth of bacteria and fungus.

127. At all times relevant, the Tennessee Defendants failed to perform the following due diligence prior to purchasing sterile compounds from NECC, as recommended by the ASHP *Guidelines on Outsourcing Sterile Compounding Services*, including, but not limited to:

a. verify whether NECC's quality processes demonstrated that NECC was a reputable and safe supplier of sterile injectable compounds;

b. determine if NECC was an accredited compounding pharmacy;

c. at least once annually, unannounced, visit NECC's corporate offices and compounding facilities and confer with NECC's corporate, pharmacy and compounding staff;

d. determine whether NECC had any product liability lawsuits filed against it for preparations compounded;

e. determine whether there had ever been recalls of any of NECC's compounded preparations;

f. evaluate NECC's standard operating procedures and manuals;

g. evaluate NECC's pharmacist technician training;

h. evaluate NECC's policies and procedures for sterility testing;

i. evaluate examples of batch reports for product being considered for outsourcing;

j. evaluate examples of quality-control reports;

k. obtain and evaluate history of the results of all NECC accreditation or regulatory surveys conducted of NECC's sites, including copies of significant regulatory actions;

l. determine if NECC could provide documentation of the end-product testing processes used to determine that compounded sterile preparations are sterile and free of pyrogens and unintended particulate matter;

m. evaluate whether NECC could assure that each compounded sterile preparation was sterile and free of pyrogens and unintended particulate matter according to professional established and accepted quality monitoring data;

n. determine whether NECC performed nonviable and viable particle testing in primary engineering controls (e.g., laminar flow workbench, biological safety cabinet) and room air according to USP chapter 797 standards;

o. determine whether NECC performed routine surface microbiological and fungal environmental monitoring to minimize contamination;

p. determine whether NECC had a policy that required validation of new or changed facilities, equipment, processes, container types, for sterility and repeatability;

q. determine whether NECC met ASHP, NIOSH and USP chapter 797 guidelines for the handling of hazardous agents;

r. evaluate NECC's quality management program, specifically as it relates to facility cleaning and validation, staff training, and competency assessment;

s. evaluate NECC's risk assessment program to ensure that medication errors are not introduced by new or increased outsourced compounding activities; and

t. determine whether NECC had a history of disciplinary or punitive actions by any regulatory agency.

E. DEFENDANTS WANTONLY EXPOSED PLAINTIFF TO THIS TOXIN

128. In 2012, NECC Related Defendants caused numerous vials of methylprednisolone acetate contaminated with fungi and other contaminants to be shipped to Specialty Surgery Center in Crossville, Tennessee. Upon information and belief, Ameridose distributed these vials to Specialty Surgery Center on behalf of NECC.

129. Specialty Surgery and Dr. Lister are sometimes collectively referred to as the

"Specialty Surgery Defendants."

130. During all relevant times, Dr. Lister was involved in Specialty Surgery's day to day operations.

131. Upon information and belief, during all relevant times, Dr. Lister was directly involved and responsible for Specialty Surgery's decision to purchase MPA from NECC.

132. Specialty Surgery, its agents and employees, and Dr. Lister knew or should have known of the dangers of using compounded drugs and specifically products compounded by NECC. Those defendants failed to undertake any appropriate due diligence to ascertain the safety and quality of NECC's products.

133. Plaintiff Wilma S. Carter was a patient at Specialty Surgery Center in Crossville, Tennessee, where Dr. Lister prescribed and administered to her, lumbar epidural steroid injections of 80 mg of MPA compounded by NECC on January 30, 2012, March 15, 2012, May 24, 2012, and September 13, 2012.

134. Unknown to Mrs. Carter, the MPA that was injected into her spine was contaminated with a fungus. The contaminated injections that were administered to Mrs. Carter were later recalled, subsequent to having been injected into her body.

135. On October 5, 2012, Mrs. Carter presented to Cumberland Medical Center complaining of a headache. She underwent a lumbar puncture which showed white blood cells. She was discharged to home.

136. Over the next six days, Mrs. Carter experienced aching and discomfort in her neck. Ms. Carter was admitted to the hospital on October 11, 2012 to undergo treatment for fungal meningitis.

137. On October 15, 2012, Mrs. Carter described worsening headaches and visual

hallucinations.

138. Mrs. Carter was discharged from the hospital on October 18, 2012 with a diagnosis of fungal meningitis.

139. Mrs. Carter's symptoms persisted, and new symptoms emerged. On October 29, 2012, Mrs. Carter reported significant pain in her low back and radiating down her leg.

140. On October 30, 2012, Mrs. Carter underwent an MRI of her lumbar spine, with and without contrast. The MRI revealed a probable epidural abscess, consistent with and epidural abscess secondary to the steroid injection.

141. Mrs. Carter was admitted to Cookville Regional Medical Center on October 30, 2012 for treatment of an epidural abscess secondary to tainted steroid injection. She was discharged to home on November 9, 2012 with a PICC line that was not removed until November 19, 2012.

142. Mrs. Carter underwent a subsequent MRI with and without contrast at Cumberland Medical Center on December 26, 2012. The MRI showed improvement, but not resolution of the abscess in her spine.

143. As of January 4, 2013, Mrs. Carter was still being followed by infectious disease and neurosurgery physicians. At that time, she was experiencing hair loss from the trauma of the incident, continued hallucinations, and remained on antifungal treatment.

144. An MRI of Mrs. Carter's lumbar spine on February 25, 2013 revealed further decrease in the size of the abscess.

145. As a result of the injuries she sustained from the tainted fungal injection, Mrs. Carter has been left with chronic back pain that cannot be treated due to the risk of recurrence of

her abscess, as well as ongoing pain, swelling, and infection, requiring ongoing medication, treatment and hospital stays.

146. Mrs. Carter has suffered mentally, emotionally, physically, and economically. She has endured painful medical procedures, trauma, headaches, stiffness, hair loss, hallucinations, back pain, and exacerbation of pre-existing medical conditions. In addition, she was forced to miss work from October 11, 2012 – January 7, 2013, and is now on light duty.

147. In addition, Plaintiff Lawrence Carter has suffered loss of consortium. The marital relationship between Mr. and Mrs. Carter has been damaged as a direct result of Mrs. Carter being injected with contaminated MPA. Mr. Carter has suffered mentally, emotionally and physically watching his wife suffer and feeling frustrated at being unable to help her feel better.

148. As of February 2013, there have been hundreds of fungal meningitis cases and infections associated with the administration of contaminated methylprednisolone acetate compounded by Defendants, with 63 deaths reported nationwide.

149. On December 20, 2012, CDC issued a Health Alert Network notice providing updated guidance and information about the ongoing multistate outbreak of fungal infections attributed to contaminated methylprednisolone acetate. In summary, the notice disclosed that many patients who received injections of the contaminated methylprednisolone acetate have developed localized spinal or paraspinal infection, including epidural abscess, phlegmon, arachnoiditis, discitis, and vertebral osteomyelitis.

150. Defendants and their agents at all times were expected to provide proper maintenance, oversight, security and control of its laboratory, facilities, distribution facility and other units. Defendants were at all times under a duty to maintain procedures that protect

patients and end consumers of the products Defendants marketed, sold, tested and/or distributed from infections and medical conditions through contaminated steroid medications or other medications.

151. Upon information and belief, the contaminated steroid medication injected into Plaintiff's body was marketed, sold, compounded, tested and/or distributed by Defendants and Plaintiff was injured as a result of their wrongful conduct.

152. The products ingredients were obtained from other entities whose identities are not yet known.

COUNT I
CIVIL CONSPIRACY

153. All allegations above are incorporated herein by reference.

154. Upon information and belief, Defendants Specialty Surgery and Dr. Lister acted in concert with the NECC Related Defendants to accomplish the unlawful purpose of circumventing Massachusetts Board of Pharmacy patient safety requirements. These Defendants accomplished that unlawful purpose buy purchasing MPA in bulk.

155. Upon information and belief, Specialty Surgery Defendants were aware of NECC's intent to bulk orders to subvert Massachusetts Board of Pharmacy requirements.

156. The concerted action of NECC and Specialty Surgery Defendants resulted in harm to Wilma S. Carter and other patients who received NECC's MPA.

157. Defendants Specialty Surgery and Dr. Lister are liable for the acts of their co-conspirator NECC.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT II
DUTY TO PREVENT FORESEEABLE HARM BY NECC
(Against Tennessee Defendants)

158. All allegations above are incorporated herein by reference.

159. Wilma S. Carter played no role in selecting the supplier of the MPA that the Specialty Surgery, through its agents and employees, injected into her spine. Wilma S. Carter relied exclusively upon Specialty Surgery, and its employees and agents, to make that selection.

160. Given the well-known dangers of bulk pharmacy compounding, the Tennessee Defendants ignored grave risks of foreseeable harm when they permitted Specialty Surgery Defendants to purchase injectable steroids from NECC in bulk and without individual prescriptions.

161. Given the well-known dangers of bulk pharmacy compounding, the Tennessee Defendants ignored grave risks of foreseeable harm when they permitted Specialty Surgery to conspire with NECC intending to hide NECC's wrongful and intentional conduct from regulators.

162. The Tennessee Defendants stood in a special relationship with Wilma S. Carter. By virtue of that special relationship, the Tennessee Defendants owed a duty to protect their patients, including Wilma S. Carter, from foreseeable harm caused by NECC's intentional conduct.

163. NECC engaged in numerous instances of intentional misconduct. That intentional misconduct included but is not limited to: (a) mass producing compounded medications and selling them in bulk in circumvention of the FDA system of regulating drug manufacturers; (b) providing false information to government regulators; (c) mass producing compounded medications and shipping those medications to Tennessee without patient specific prescriptions

in violation of Massachusetts Board of Pharmacy Rules and Tenn. Code Ann. § 63-10-204(4); (d) enlisting the aid of its customers in creating false paper trails designed to hide its misconduct from government regulators; and (e) mass producing purportedly sterile injectable drugs under filthy conditions in violation of regulations promulgated by the Massachusetts Board of Registration in Pharmacy and found at 247 CMR 6.02(1).

164. The Tennessee Defendants breached their duty to their patients, including Wilma S. Carter, by failing to protect them from the foreseeable harm caused by NECC's intentional conduct.

165. As a direct and proximate result of the Tennessee Defendants' breach of their duties, Wilma S. Carter suffered the injuries alleged in this Complaint.

166. Because the Tennessee Defendants owed Wilma S. Carter a duty to protect her from NECC's conduct, the Tennessee Defendants' fault cannot be reduced by any fault attributable to NECC. Accordingly, the Tennessee Defendants are jointly and severally liable for all harm caused by NECC's conduct.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT III
NEGLIGENCE
(Against NECC Related Defendants)

167. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

168. As the designer, tester, compounder, seller, marketer and/or distributor of consumer products, the NECC Related Defendants owed a duty to Plaintiff Wilma S. Carter to

comply with existing standards of care, and to exercise due care, in providing a safe and quality product to Mrs. Carter.

169. Specifically, but without limitation:

i. Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin owed Plaintiff a duty to provide MPA that was safe and free of contamination; and

ii. ARL owed Plaintiff a duty to properly conduct tests to insure that the methylprednisolone acetate was safe and free of contamination.

170. The NECC Related Defendants breached those duties and were otherwise negligent in their design, compounding, sale, testing, marketing and distribution of the recalled steroid medication, which was administered to Mrs. Carter. The NECC Related Defendants failed to exercise due care in accordance with the standard of care and skill required of, and ordinarily exercised by, a designer, compounder, tester, seller, marketer and distributor of steroid medications, as licensed to do so by the Commonwealth of Massachusetts. The NECC Related Defendants, by and through supervisors, staff and agents engaged in designing, compounding, sales, testing, marketing and distributing MPA in a negligent manner.

171. The NECC Related Defendants further breached those duties by failing to hold the components of the recalled medications; by failing to properly design, compound, test, and distribute MPA so that it would not be contaminated with a fungus; by failing to properly maintain its facilities where it compounded its medications in a clean, sanitary manner; by failing to oversee the security and quality control of its compounding and distribution facilities; and by allowing contaminated and unsafe medications compounded to reach the stream of commerce for use by Plaintiff.

172. The NECC Related Defendants breached the duties owed to Plaintiff by failing to use reasonable care in designing, compounding, testing, marketing, distributing and/or selling methylprednisolone acetate.

173. The negligence of Ameridose, GDC, MSM/MSMSW, Gregory Conigliaro, Douglas Conigliaro, Carla Conigliaro, Barry Cadden, Lisa Cadden and Glenn Chin was a proximate cause of Plaintffs' injuries.

174. Plaintiff was exposed to fungal meningitis through NECC's contaminated steroid that was injected into her by Dr. Lister at Specialty Surgery Center.

175. As a direct and proximate result of the negligence of the NECC Related Defendants, and being injected with a contaminated dose of MPA, Plaintiffs suffered injuries, conscious pain and suffering, emotional distress, economic loss, and other injuries.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT IV
NEGLIGENCE PER SE
(Against All NECC Related Defendants)

176. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

177. The NECC Related Defendants owed Plaintiffs a duty to maintain the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

178. The NECC Related Defendants breached the duties owed to Plaintiff by failing to use reasonable care in maintaining the premises of the pharmacy "in a clean and sanitary manner[,]" 247 CMR 6.02(1), and free from contamination.

179. The NECC Related Defendants also violated Massachusetts' laws and its pharmacy licensing obligations.

180. As a direct and proximate result of the negligence of the NECC Related Defendants, and being injected with contaminated doses of MPA, Plaintiffs suffered injuries, conscious pain and suffering, emotional distress, economic loss and other damages.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT V
NEGLIGENT SUPERVISION
(Against All NECC Related Defendants)

181. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

182. The NECC Related Defendants had an obligation and duty to exercise due care, and comply with the then existing standard of care, to investigate and hire professional and competent employees to create, test, package, market and distribute the compounded medications and to maintain the facility and its premises, and to make sure the compounded drugs did not create any harm or risk to the Plaintiff and others who received the compounded medications.

183. In breach of those duties, Defendants failed to exercise due care and failed to supervise their employee(s) or agent(s), who were at all times working within the scope of their employment and authority. Specifically, and without limitation:

i. the Defendants failed to monitor and test the steroid medication and were otherwise negligent in supervision of their employees;

ii. Defendants also failed to monitor and supervise the testing of the compounded medications; and

iii. the Defendants were negligent in hiring, training, and supervising their employees.

184. The Defendants knew, or should have known, that the employee or agent did not follow proper procedures and knew or should have known of the risks created by failing to do so.

185. As a direct and proximate cause of the breach of those duties, the Defendants permitted the steroid to become contaminated and distributed to patients including Mrs. Carter.

186. As a direct and proximate result of the negligence of the Defendants, and being injected with contaminated methylprednisolone acetate, Plaintiffs suffered injuries, conscious pain and suffering, emotional distress, economic loss and other injuries.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VI
PUBLIC NUISANCE
(Against Barry Cadden, Gregory Conigliaro and GDC)

187. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

188. At all relevant times, Barry Cadden, Gregory Conigliaro and/or GDC were in control of the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

189. Barry Cadden, Gregory Conigliaro and GDC owed a duty to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts in a condition that was free from contamination.

190. Barry Cadden, Gregory Conigliaro and GDC failed to exercise reasonable care in maintaining the property and improvements at 697 Waverly Street, Framingham, Massachusetts.

191. The failure by Barry Cadden, Gregory Conigliaro and GDC to maintain the property and improvements at 697 Waverly Street, Framingham, Massachusetts was a proximate cause of the multistate epidemic of fungal meningitis and infections caused by the contaminated methylprednisolone acetate.

192. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public health and the public safety.

193. Barry Cadden, Gregory Conigliaro and GDC unreasonably and significantly interfered with the public right expressed in 247 CMR 6.02(1).

194. The public nuisance created by Barry Cadden, Gregory Conigliaro and GDC caused Plaintiffs' injuries.

195. As a direct and proximate result of the acts and omissions of the Defendants, and being injected with contaminated doses of methylprednisolone acetate, Plaintiffs suffered injuries, conscious pain and suffering, emotional distress, economic loss, and other damages.

WHEREFORE, the Plaintiffs demand judgment against Defendants, jointly and severally, on Count VIII of this Complaint, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VII
DECEPTIVE TRADE AND BUSINESS PRACTICES ACT VIOLATIONS[2]
(Against All NECC Related Defendants)

196. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, and further allege:

197. The NECC Related Defendants engaged in trade and commerce within the Commonwealth of Massachusetts.

198. The NECC Related Defendants' negligence, negligent supervision, violation of warranties and nuisance constitutes a violation of the Act. The NECC Related Defendants' failure to perform and fulfill its promises, representations, and obligations under the product's warranties, constitutes an actionable violation.

199. As described herein, the NECC Related Defendants represented that their product had characteristics, uses and benefits that it did not have.

200. As describe herein, the NECC Related Defendants represented that their product was of a particular standard, quality and grade that they either knew or should have known was not of the standard, quality or grade described.

201. The NECC Related Defendants failed to provide accurate disclosures of all material information before Plaintiff and her providers transacted to use Defendants' product.

202. The NECC Related Defendants willfully and knowingly failed to abide by regulations, laws and guidelines set forth to protect consumer safety, including Plaintiffs, constituting a violation of the Act.

203. The NECC Related Defendants' willful and knowing withholding of important

[2] Pursuant to section E., p. 5 of this Court's June 28, 2013 Case Management Order, MDL Order No. 6, NECC Related Defendants have agreed to waive pre-suit notice requirements, including MGL c. 93A pre-suit demand requirement.

safety information and critical product information constitutes a violation of the Act.

204. The NECC Related Defendants actively, knowingly, and deceptively concealed their knowledge of their product's dangerous properties and life-threatening risks. This conduct evidences bad faith and unfair and deceptive practices.

205. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of confusion and misunderstanding.

206. The NECC Related Defendants engaged in the conduct as described herein that created a likelihood of causing injury to unknowing consumers, including Plaintiffs.

207. The NECC Related Defendants' conduct as described herein constituted unfair and deceptive acts and practices, including, but not limited to:

i. Misrepresenting the nature, quality, and characteristics about the product;

ii. Unfairly violating regulations, laws and guidelines set forth to protect consumer safety;

iii. Unfairly exposing unknowing consumers, including Plaintiffs, to significant, unnecessary risk of harm and actual harm and injury; and

iv. All other unfair and deceptive acts set forth herein

208. The practices described herein are unfair because they offend public policy as established by statutes, the common law, or otherwise. Additionally the NECC Related Defendants were unethical and unscrupulous, and caused substantial injury to consumers. The NECC Related Defendants engaged in an unconscionable actions and course of action.

209. The NECC Related Defendants willfully engaged in the conduct described herein, which they knew were deceptive, in the course of retail business, trade and commerce, and had a deleterious impact on the public interest.

210. The NECC Related Defendants are liable to Plaintiffs for all statutory, direct and consequential damages, and fees and costs resulting from this breach, including multiple damages.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT VIII
PRODUCT LIABILITY CLAIMS
(Against Specialty Surgery)

246. The MPA injected into Wilma S. Carter's lumbar spine in January, March, May and September 2012 was compounded by NECC.

247. On December 21, 2012, NECC filed a voluntary petition pursuant to Chapter 11 of Title 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of Massachusetts, In re: New England Compounding Pharmacy, Inc., case no. 12:19882-HJB.

248. Pursuant to 11 U.S.C. § 362(a)(1) certain actions against NECC are stayed following its bankruptcy petition.

249. Plaintiffs could have commenced an action in this court seeking to recover on a claim and seeking a judgment against NECC before December 21, 2012.

250. Plaintiffs' claims that arose before NECC's petition in bankruptcy are subject to the automatic stay provisions of 11 U.S.C. § 362(a)(1).

251. NECC has ceased operations.

252. NECC is unable to pay its debts as they fall due.

253. NECC is unable to pay its debts in the ordinary course of its business.

254. NECC's liabilities exceed its assets.

255. NECC is insolvent.

256. On July 24, 2013, The United States Bankruptcy Court for the District of Massachusetts in In re: New England Compounding Pharmacy, Inc., Case no. 12-19882-HJB, ordered that with respect to certain claims, including those asserted by Plaintiffs in this lawsuit, NECC is presently insolvent and has been insolvent at all times since the petition date.

257. Specialty Surgery procured the MPA injected into Wilma S. Carter's lumbar spine from NECC.

258. NECC's product (MPA) was defective and unreasonably dangerous when it left NECC's control because it was contaminated with lethal pathogens.

259. NECC's MPA was in substantially the same condition at the time that Specialty Surgery Center injected it into Wilma S. Carter's lumbar spine in January, March, May and September of 2012.

260. Specialty Surgery Center charged Wilma S. Carter for epidural steroid injections administered to her.

261. Specialty Surgery Center acted as a seller or distributor of MPA compounded by NECC when it sold and administered epidural steroid injections to patients, including Wilma S. Carter.

262. Specialty Surgery Center was engaged in the business of selling MPA compounded by NECC.

263. Accordingly, Specialty Surgery Center is a "seller" as defined by Tenn. Code Ann. § 29-28-102(7).

264. Tenn. Code Ann. § 29-28-106(4) authorizes Plaintiffs Wilma S. Carter and Lawrence Carter to prosecute product liability claims against Specialty Surgery Center as the

seller of the MPA injected into Wilma S. Carter's lumbar spine because the compounder of the product, NECC, cannot be served with process in this state.

265. Tenn. Code Ann. § 29-28-106(5) authorizes Plaintiffs Wilma S. Carter and Lawrence Carter to prosecute product liability claims against Specialty Surgery Center as the seller of the MPA injected into Wilma S. Carter's lumbar spine because the compounder of the product, NECC, has been judicially declared insolvent.

266. The MPA that Specialty Surgery Center injected into Wilma S. Carter's lumbar spine was unreasonably dangerous and defective at the time it left their control because it was contaminated with lethal pathogens.

267. Specifically, the MPA was in a defective condition and unreasonably dangerous at all relevant times because it was unsafe for normal or anticipated handling as defined by Tenn. Code Ann. § 29-28-102(2).

268. The MPA sold and distributed by Specialty Surgery Center was neither merchantable nor fit for the purpose for which it was produced and sold. Accordingly, Specialty Surgery Center breached its warranties, both express and implied, as stated in Tenn. Code Ann. §§ 47-2-313, 47-2-314, and 47-2-315, including their warranty of fitness for a particular purpose.

269. Specialty Surgery Center is strictly liable for the injuries and losses caused by the unreasonably dangerous and defective steroids injected into Wilma S. Carter's lumbar spine.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT IX
DUTY TO PREVENT FORESEEABLE HARM
(Against Tennessee Defendants)

235. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if

fully set forth herein at length, and further alleges:

236. Plaintiff played no role in selecting the supplier of the MPA that Specialty Surgery, through its agents and employees, injected into her spine. Plaintiff relied exclusively upon St. Thomas Neurosurgical, and its employees and agents, to make that selection.

237. Given the well-known dangers of bulk pharmacy compounding, the Tennessee Defendants ignored grave risks of foreseeable harm when they permitted Specialty Surgery to purchase injectable steroids from NECC in bulk and without individual prescriptions.

238. Given the well-known dangers of bulk pharmacy compounding, the Tennessee Defendants ignored grave risks of foreseeable harm when they permitted Specialty Surgery to conspire with NECC in the creation of false paper trails intended to hide NECC's wrongful and intentional conduct from regulators.

239. The Tennessee Defendants stood in a special relationship with Plaintiff. By virtue of that special relationship, the Tennessee Defendants owed a duty to protect their patients, including Plaintiff, from foreseeable harm caused by NECC's intentional conduct. NECC engaged in numerous instances of intentional misconduct. That intentional misconduct included but is not limited to: (a) mass producing compounded medications and selling them in bulk in circumvention of the FDA system of regulating drug manufactures; (b) providing false information to government regulators; (c) mass producing compounded medications and shipping those medications to Tennessee without patient specific prescriptions in violation of Massachusetts Board of Pharmacy Rules and Tenn. Code Ann. § 63-10-204(4); (d) enlisting the aid of its customers (including Specialty Surgery) in creating false paper trails designed to hide its misconduct from government regulators; and (e) mass producing purportedly sterile injectable

drugs under filthy conditions in violation of regulations promulgated by the Massachusetts Board of Registration in Pharmacy and found at 24 7 CMR 6.02(1).

240. The Tennessee Defendants breached their duty to their patients, including Plaintiff, by failing to protect them from the foreseeable harm caused by NECC's intentional conduct.

241. As a direct and proximate result of the Tennessee Defendants' breach of their duties, Plaintiff suffered physical injuries.

242. Because the Tennessee Defendants owed Plaintiff a duty to protect her from NECC's conduct, the Tennessee Defendants' fault cannot be reduced by any fault attributable to NECC. Accordingly, the Tennessee Defendants are jointly and severally liable for all harm caused by NECC's conduct.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT X
OTHER CLAIMS AGAINST SPECIALTY SURGERY

243. Specialty Surgery's decision to select NECC as its supplier of purportedly sterile injectable steroids was negligent.

244. Specialty Surgery knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.

245. Specialty Surgery acting through its agents, employees, and representatives negligently and recklessly purchased contaminated MPA from NECC.

246. Specialty Surgery failed to conduct appropriate due diligence regarding NECC. Had they done so, any reasonable purchaser would have declined to purchase from NECC.

247. Specialty Surgery, acting though its physicians, nurses, managers, agents, and employees, was negligent in its care and treatment of Wilma S. Carter. Such care and treatment fell below the recognized standard of acceptable professional practice for pain management and drug procurement practices in this or similar communities and was a proximate cause of Wilma S. Carter's injuries and damages. Specifically, Specialty Surgery was negligent and rendered substandard care in the following respects:

a. procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

b. failed to visit NECC's facilities before procuring spinal injection medicines from that company;

c. failed to investigate and exercise sufficient due diligence before administering injectable steroids procured from NECC, including its failure to investigate or inquire concerning NECC's compounding practices;

d. failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;

e. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;

f. failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from that company;

g. failed to keep abreast of the dangers of sterile compounding;

h. purchased compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions;

i. failed to adequately supervise and train the physicians, nurses, agents and employees who ordered MPA from NECC;

j. failed to follow its own formulary that would have prevented the use of MPA compounded by NECC in epidural steroid injections;

k. failed to implement policies and procedures that would prevent the procurement of purportedly sterile injectable medications from an out-of-state compounding pharmacy with deplorable sterility procedures, a checkered regulatory past, product recall problems, and a history of product liability suits;

l. injected steroids into Wilma S. Carter's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens; and

m. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives.

248. As a direct and proximate result of the negligent acts and omissions described above, Wilma S. Carter suffered injuries and damages that would not have otherwise occurred.

249. The physicians, nurses, agents, employees and representatives who decided to procure MPA from NECC and who injected that steroid into Wilma S. Carter's lumbar spine were employees or agents of Specialty Surgery, and they were acting within the course and scope of their employment or agency. Accordingly, Specialty Surgery is liable for the consequences of said person's or persons' conduct pursuant to the doctrine of *respondeat superior*.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT XI
AGENCY
(Specialty Surgery)

250. All allegations above are incorporated herein by reference.

251. At all times relevant herein, NECC was acting as an agent of Specialty Surgery in compounding drugs to be administered to the Decedent by said defendants.

252. A consensual fiduciary relationship arose when Specialty Surgery contracted with NECC to procure compounded drugs from NECC for their patients, including Decedent.

253. Specialty Surgery manifested assent for NECC to act as their agent, and on their behalf, when they contracted with NECC to procure compounded drugs from NECC to administer to their patients, including Plaintiff.

254. NECC consented to act as Specialty Surgery's agent, and in its interest, when compounding, selling and delivering its compounded drugs to them, to be sold and administered to their patients, including Plaintiff.

255. At all times relevant herein, NECC acted within the scope of its agency with Specialty Surgery. As set forth herein, NECC acted negligently and or exhibited gross negligence in the compounding of NECC contaminated drugs.

256. Specialty Surgery controlled the procurement of the drugs from NECC to be sold and administered to their patients, including Plaintiff.

257. As a result, Specialty Surgery is responsible for the negligence, gross negligence and wrongful conduct of NECC in compounding the contaminated drugs administered to Plaintiff.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT XII
CLAIMS AGAINST KENNETH R. LISTER, MD

258. Upon information and belief, Dr. Lister was involved in making the decision to purchase MPA from NECC.

259. Upon information and belief, Dr. Lister was involved in managing the day to day operations at Specialty Surgery.

260. Dr. Lister was negligent in his selection of NECC as a supplier of MPA to Specialty Surgery.

261. Dr. Lister knew or should have known that NECC was not a safe and reputable supplier of injectable steroids such as MPA.

262. Dr. Lister failed to conduct appropriate due diligence regarding NECC. Had he done so, any reasonable purchaser would have declined to purchase from NECC.

263. Dr. Lister's decision to purchase MPA in bulk from NECC was based solely on price.

264. Dr. Lister was negligent in his care and treatment of Wilma S. Carter. Such care and treatment fell below the recognized standard of acceptable professional practice for physicians in similar circumstances in this or similar communities and was a proximate cause of Wilma S. Carter's injuries and damages. Specifically, Dr. Lister was negligent and rendered substandard care in the following respects:

a. procured injectable steroids from NECC, for the purpose of injecting those medications into the spines of patients for profit, without conducting adequate due diligence regarding whether NECC was a reputable and safe supplier of sterile injectable compounds;

b. failed to visit NECC's facilities before procuring spinal injection medicines from that company;

c. failed to investigate and exercise sufficient due diligence before administering injectable steroids procured from NECC, including its failure to investigate or inquire concerning NECC's compounding practices;

d. failed to determine whether NECC had a history of recalling compounded medications before procuring spinal injection medicines from that company;

e. failed to investigate NECC's regulatory history with the FDA and/or the Massachusetts Board of Registration in Pharmacy before procuring spinal injection medicines from that company;

f. failed to determine whether NECC had a history of product liability suits before procuring spinal injection medicines from that company;

g. failed to keep abreast of the dangers of sterile compounding;

h. injected steroids into Wilma S. Carter's lumbar spine without taking reasonable steps to ensure that those medicines were from a reputable supplier and were not contaminated with lethal pathogens;

i. approved, facilitated or permitted the purchase of MPA from NECC because it was less expensive than safer alternatives;

j. purchased compounded injectable steroids in bulk from NECC without using patient specific individual prescriptions; and

265. As a direct and proximate result of the negligent acts and omissions described above, Wilma S. Carter suffered injuries and damages that would not have otherwise occurred.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

COUNT XIII
LOSS OF CONSORTIUM
(Against All Defendants)

266. Plaintiffs incorporate by reference all other paragraphs in this Complaint as if fully set forth herein at length, as further allege:

267. Plaintiffs, at all times relevant hereto, were and continue to be husband and wife.

268. Plaintiff, Lawrence Carter, as a result of the injuries sustained by Plaintiff, Wilma S. Carter, described above, has suffered loss of consortium. He has suffered, and will continue to suffer in the future, mental anguish, the loss of support, love, companionship, affection, society, sexual relations, solace and other damages.

269. In addition, the marital association between Mr. and Mrs. Carter has been damaged as a direct result of Mrs. Carter's use of the Defendants' defective and contaminated steroid injection.

WHEREFORE, the Plaintiffs demand judgment against the Defendants, jointly and severally, in an amount that will justly compensate for the damages, together with interest, costs and their attorney fees incurred in this action, all within the jurisdictional limits of this Court.

PUNITIVE DAMAGES

270. The above described acts and omissions on the part of the Defendants were reckless and intentional. Defendants were aware of, but consciously disregarded, a substantial and unjustifiable risk of such a nature that their disregard constitutes a gross deviation from the standard of care that an ordinary person would exercise under all the circumstances. Plaintiffs therefore are entitled to an award of punitive damages against the Defendants.

CAPS FOUND IN TENN. CODE ANN. § 29-39-102 AND § 29-39-104 ARE UNCONSTITUTIONAL AND VOID *AB INITIO*

271. Plaintiffs seek a judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201, declaring that the caps on personal injury and punitive damages set forth in Tenn. Code Ann. § 29-39-102 and Tenn. Code Ann. § 29-39-104 are an unconstitutional deprivation of the right to trial by jury set forth in Article I, Section 6, of the Constitution of the State of Tennessee, which provides that the right of trial by jury shall remain inviolate, and violate the provisions of Article XI, Section 16, of the Constitution of the State of Tennessee which absolutely precludes the Legislature from exercising any legislative power to remove or restrict the right of juries in civil cases to determine damages.

272. On October 1, 2011, the Tennessee Civil Justice Act went into effect, enacting "caps" in all Tennessee personal injury cases for non-economic damages and punitive damages.